Attorney Docket No. 57636-8127.US01

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Laus, *et al.*	
APPLICATION NO.: 10/666,122	EXAMINER: BRISTOL, LYNN ANNE
FILED: September 19, 2003	ART UNIT: 1643
FOR: IMMUNOTHERAPEUTIC COMPOSITIONS AND METHODS FOR THE TREATMENT OF MODERATELY TO WELL-DIFFERENTIATED CANCERS	CONF. NO: 8703

Declaration under 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Robert B. Sims, M.D., declare and affirm as follows:

1. I have been employed by Dendreon Corporation (hereinafter "Dendreon") since 2003, and was promoted to the position of Senior Medical Director in 2007.

2. I received my Bachelors' degree in Biology from the University of Oregon in 1979 and my M.D. from Oregon Health Sciences University, School of Medicine in 1983. I completed three years of internal medicine residency training at the N.Y.U. Medical Center in 1986 and completed three years of hematolgy oncology fellowship training at Temple University Medical Center and Fox Chase Cancer Center in 1989. Prior to my employment at Dendreon, I was Associate Medical Director at NeoRx Corporation from 2002-2003. I have been an Attending physician at Hematology-Oncology Northwest Specialties, PLLC since 2001. I am Board certified in Internal Medicine, Hematology and Medical Oncology.

3. Key areas of my technical expertise are oncology and medical research.

4. A Gleason score is used to help evaluate the prognosis of men with prostate cancer and is assigned to a patient's prostate cancer based upon its microscopic appearance after tissue biopsy or prostatectomy. Higher Gleason scores are assigned to a cancer that is more aggressive, and thus, cancers with higher Gleason scores are associated with a worse prognosis. A Gleason score ranges from two to ten. A Gleason score of two is associated with the best prognosis and a score of ten with the worst. The final Gleason score is the sum of two

scores, each ranging from one to five: the "primary grade" represents the majority of the tumor (observed in greater than 50% of the total pattern), and the "secondary grade" represents the minority of the tumor (between 5 and 50% of the pattern of the total cancer). These scores are then added to obtain the final Gleason score.

Gleason Grades 1 through 5 have the following features:

Grade 1 - The cancerous prostate closely resembles normal prostate tissue. The glands are small, well-formed, and closely packed.

Grade 2 - The tissue still has well-formed glands, but they are larger and have more tissue between them.

Grade 3 - The tissue still has recognizable glands, but the cells are darker. At high magnification, some of these cells have left the glands and are beginning to invade the surrounding tissue.

Grade 4 - The tissue has few recognizable glands. Many cells are invading the surrounding tissue.

Grade 5 - The tissue does not have recognizable glands. There are often just sheets of cells throughout the surrounding tissue.

For example, a prostate biopsy specimen may exhibit two different patterns, one which is assigned a number two and the other a number three. The final Gleason score in this case would be five. In my over 20 years of medical experience, I have not known a patient to have a "mixed" final Gleason score. It is possible, however, for a single patient to have a different final Gleason score if the patient is evaluated by a different pathologist.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

7/7/08
Date

Robert B. Sims, M.D.